Procedural surgical RCTs in daily practice: do surgeons adopt or is it just a waste of time?

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Abstract: OBJECTIVE: To assess the adoption of recommendation from randomized clinical trials (RCTs) and investigate factors favoring or preventing adoption. BACKGROUND: RCT are considered to be the cornerstone of evidence-based medicine by representing the highest level of evidence. As such, we expect RCT's recommendations to be followed rigorously in daily surgical practice. METHODS: We performed a structured search for RCTs published in the medical and surgical literature from 2009 to 2013, allowing a minimum of 5-year follow-up to convincingly test implementation. We focused on comparative technical or procedural RCTs trials addressing the domains of general, colorectal, hepatobiliary, upper gastrointestinal and vascular surgery. In a second step we composed a survey of 29 questions among ESA members as well as collaborators from their institutions to investigate the adoption of surgical RCTs recommendation. RESULTS: The survey based on 36 RCTs (median 5-yr citation index 85 (24-474), from 21 different countries, published in 15 high-ranked journals with a median impact factor of 3.3 (1.23-7.9) at the time of publication. Overall, less than half of the respondents (47%) appeared to adhere to the recommendations of a specific RCT within their field of expertise, even when included in formal guidelines. Adoption of a new surgical practice was favored by watching videos (46%) as well as assisting live operations (18%), while skepticism regarding the methodology of a surgical RCT (40%) appears to be the major reason to resist adoption. CONCLUSION: In conclusion, surgical RCTs appear to have moderate impact on daily surgical practice. While RCTs are still accepted to provide the highest level of evidence, alternative methods of evaluating surgical innovations should also be explored.

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Procedural Surgical RCTs in Daily Practice

Do Surgeons Adopt Or Is It Just a Waste of Time?

Christian E. Oberkofler, MD, Jacob F. Hamming, MD, PhD,† Roxane D. Staiger, MD,* Philippe Brosi, MD,* Sebastiano Biondo, MD, PhD,‡ Olivier Farges, MD, PhD,§ Dink A. Legemate, MD, PhD,¶ Mario Morino, MD,|| Antonio D. Pinna, MD,** Hugo Pinto-Marques, MD, PhD,†† John V. Reynolds, MD,‡‡ Ricardo Robles Campos, MD, PhD,§§ Xavier Rogiers, MD,¶¶ Kjetil Soreide, MD, PhD,|||| Milo A. Puhan, MD, PhD,*** Pierre-Alain Clavien, MD, PhD,* and Inne Borel Rinkes, MD, PhD†††✉*

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Conclusion: In conclusion, surgical RCTs appear to have moderate impact on daily surgical practice. While RCTs are still accepted to provide the highest level of evidence, alternative methods of evaluating surgical innovations should also be explored.

From the *Department of Surgery and Transplantation, University Hospital Zurich, Zurich, Switzerland,; †Department of Vascular Surgery, Leiden University Medical Center, Leiden, The Netherlands; ‡Department of General and Digestive Surgery, Bellvitge University Hospital, Barcelona, Spain; §Department of Surgery and Transplantation, Hôpital Beaujon, Clichy, France; ¶Department of Surgery, Amsterdam UMC, University of Amsterdam, Amsterdam, The Netherlands; ||Department of Digestive Surgery, Hospital San Giovanni Battista, University of Torino, Torino, Italy; **Digestive Disease Institute, Cleveland Clinic, Abu Dhabi, United Arab Emirates; ††Department of Surgery, Curry Cabral Hospital, Lisbon, Portugal; ‡‡Department of General Surgery, St. James's Hospital, Dublin, Ireland; §§Department of Surgery and Transplantation, Virgen de la Arrixaca Clinic and University Hospital, Murcia, Spain; ¶¶Department of Surgery and Transplantation, Gent University Hospital and Medical School UZG, Gent, Belgium; ||||Department of Clinical Medicine, Gastrointestinal Surgery, HPB unit, Stavanger, Norway; ***Epidemiology, Biostatistics and Prevention Institute, University of Zurich, Zurich, Switzerland; and †††Department Surgical Oncology, Endocrine and GI Surgery, University Hospital Utrecht, Utrecht, The Netherlands.

✉I.H.M.BorelRinkes@umcutrecht.nl.

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Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.[1,2] Practicing evidence-based medicine implies integrating individual clinical expertise with the best available external clinical evidence from systematic research and with patients' values, preferences, and expectations.[3] Randomized controlled trials (RCTs) have become the cornerstone of modern clinical research in medicine as they represent the highest level of scientific evidence presently available.[4]

Surgeons have been accused of lagging behind their medical colleagues in embracing evidence-based medicine, as surgical RCTs reportedly accounted for only 3% to 7% of surgical articles published.[5–8] A comparison between 4 leading surgical versus medical journals over a 2-year period revealed a 5-fold higher number of medical RCTs in the latter compared with surgical trials.[9] In addition, up to 40% of surgical patients were observed not to receive evidence-based care.[10,11] And although there has been a noticeable improvement in the quantity and quality of published surgical studies in recent years, widespread practice of evidence-based surgery remains still modest at best.[10,12,13]

Proposed reasons for the relative paucity of RCTs from the surgical disciplines include problematic randomization resulting from surgeon *and* patient preferences; that is unbalanced equipoise, difficulties in reducing bias including the difficulty of blinding or standardization of procedures, and the rapid pace of changes techniques rendering outcomes of lengthy RCTs irrelevant by the time of their publication.[14] Today, surgical RCTs are discontinued in up to 43%,[15] mainly because of slow recruiting, inability of the trial to achieve its objectives, administrative problems, and costs.[15,16]

Surprisingly, little is known about the clinical adoption of available information gathered from surgical RCTs that have overcome all these hurdles and were eventually published. One would expect surgical practice to rigorously follow the results of level 1 evidence trial. Hints exist that this might not be the case due to many factors such as surgeons' reluctance to change, ignorance, or even ego-related issues. In fact, examples of RCT evidence exist that convincingly oppose current clinical practice, but appear unable to change surgical policy. In vascular surgery, for instance, EndoVascular Aneurysm Repair (EVAR) has been proven to reduce short-term mortality and morbidity while long-term results appear to be similar and cost effectiveness is being seriously questioned due to high cost of materials and high reintervention rates. Still, EVAR is used in up to 80% of all elective patients with an abdominal aneurysm.[17]

The aim of this special article was to assess the impact of high-quality RCTs in surgery and the adoption of RCT outcomes in

daily surgical practice. To this end, a systematic evaluation of procedural surgical RCTs was carried out, followed by a survey among members of the European Surgical Association in an attempt to understand the underlying factors preventing adoption of high level of evidence information.

METHODS

We performed a structured search for RCTs published in the medical and surgical literature from 2009 to 2013 by screening RCTs in EMBASE (11,752) and Medline (22,723) using the search terms (RCT, surgery, surgical device). This period was chosen in order to ascertain a minimum of 5-year follow-up, allowing sufficient time for dissemination of the published results into surgical practice, as well as finding their way into clinical guidelines. We focused on trials addressing the domains of general (mostly parietology), colorectal, hepatobiliary, upper gastrointestinal and vascular surgery. Only comparative technical or procedural RCTs were selected that produced statistically significantly different results that advocate a specific procedure or procedural change. Excluded were pilot studies, RCTs on drug efficacy or investigating training results, as well as cost effectiveness studies and RCTs which treated the same topic during the investigated time period, but with contradictory outcomes.

Next, the selected RCTs underwent a qualitative assessment as to their risk of bias. Most of these RCTs lack a structured reporting according to CONSORT NTP (Consolidated Standards of Reporting Trials assessing nonpharmacologic treatment),[18,19] which implied a lack in *reporting* quality. To determine the internal validity of the selected trials, the RCTs were further assessed using the Cochrane criteria for judging risk of bias,[20] including random sequence generation, allocation concealment, blinding of participants and personnel, as well as blinding of outcome assessment. The intention was to solely include RCTs with low risk of bias (Fig. 1 and Table 1).

We composed a survey of 22 questions (Addendum 1, http://links.lww.com/SLA/B749) addressing a selection of 36 representative RCTs (Addendum 2, http://links.lww.com/SLA/B749) in the field of general (6 questions), colorectal (7 questions), HPB (6 questions), upper GI (2 questions), and vascular surgery (1 question). The recommendations of 14 (39%) of these RCTs had been incorporated into some guidelines. Moreover, 7 questions relating to the reasons for surgeons' adoption or dismissal of RCTs' recommendations were included in the survey (Addendum 1: online Survey questions, http://links.lww.com/SLA/B749). This questionnaire was first tested on 48 surgeons practicing in academic and nonacademic centers in Switzerland. Following several adaptations in the phrasing of the questions, it was distributed among 300 members of the European Surgical Association via the online questionnaire tool SurveyMonkey.com. Moreover, ESA members and coauthors of this collaborative work circulated the questionnaire among 10 colleagues in their respective institutions. Respondents were encouraged not to address issues that they considered outside their field of expertise. All replies were analyzed to identify the degree of adherence to the recommendations of the respective RCTs.

Statistical Analysis

For each of the 22 questions the percentage of answers corresponding to the respective RCT's recommendation was determined. To evaluate possible parameters influencing surgeons' acceptance of the results of RCTs (''corresponding answer"), a linear regression model was fitted with the proportion of ''corresponding'' answers as the dependent variable and correlated with the domain of surgery, year of RCT publication, impact factor of the journal at the time of publication, 5-year citation index, number of included centers and total cohort size in each study, as well as the admission of RCT results into a guideline. In a second step, we also added gender, surgical specialty, and years of experience after board certification into the model. The goodness-of-fit of the model was expressed by R2, P values ≤ 0.05 were considered statistically significant. For all statistical analyses, the program R was used.[21]

RESULTS

After screening 34,475 RCTs, we identified 2199 trials in the field of surgery (6.4%) (Fig. 1), which were published in recognized journals benefiting from an Impact Factor. Further selection restricted the study to only comparative technical or procedural RCTs in the domains described above, leaving 506 eligible trials, of which 219 produced results that were statistically different between treatment/procedure groups. Robustness evaluation regarding randomization and blinding resulted in a final delineation of 112 RCTs that could be incorporated into our questionnaire (Fig. 1). These RCTs originated from 30 different countries and were published in 15 surgical journals (*Annals of Surgery* 18 (16%); *British Journal of Surgery* 15 (13%); *Surgical Endoscopy* 12 (10%); *Diseases of the Colon and Rectum* 7 (6%); *World Journal of Surgery* 7 (6%); others 53 (47%)). The median 5-year citation index was 54 (range 3–474) and the cohort size of patients included into the RCTs was 100 (range 24–1000). Most (67%) of the RCTs were conducted in 1 single center (range 1–41) (Table 1). Out of these RCTs, we build our questionnaire including 36 RCTs. The selection of RCTs was done using a pragmatic approach. Based on the frequency of RCTs of the respective surgical domain, we chose RCTs covering topics likely encountered in daily practice and added to them a few specialized questions for each surgical domain. Those RCTs were comparable with the 112 RCTs regarding Journals of publication, Impact factor, as well as Citation Index.

Our internationally conducted survey on surgeons' adoption of RCT recommendations included 22 questions on abdominal and vascular surgery, based on 36 RCTs (median 5-yr citation index (CI) 85 (24–474), from 21 different countries, published in 15 high-ranked journals with a median impact factor (IF) of 3.3 (1.23–7.9) at the time of publication. Hundred and thirty international surgeons (34.2%) completed the survey, 82% of whom were male. The median surgical expertise after board certification was 16 years (range 1–48). Among the respondents were 27% general surgeons, 22% colorectal surgeons, 22% hepato-pancreatico-biliary surgeons, 13% upper gastrointestinal surgeons, 6% vascular surgeons, and 10% others (Table 2).

Overall, less than half of the respondents appear to adhere to the recommendations of a specific RCT within their field of expertise with a median of 47% ''corresponding'' answers. However, a very wide range of proportions of answers corresponding to adoption of RCT recommendation was found within each of the surgical fields: (0–73%) (Fig. 2). General surgeons showed a range of 3% to 71% to their adoption of RCTs recommendation, colorectal surgeons from 0% to 94%, HPB from 10% to 76%, and UGI from 23% to 84% (Table 3). Interestingly, in all fields of expertise, there were trials that had either a rather high ($>$ 60–65%), or a low adherence percentage ($<$20–25%), indicating that the respondents were relatively consistent in their opinion regarding specific RCT's recommendations (Table 3). In the regression analysis, none of the factors that might explain the proportion of ''corresponding'' answers showed a statistically significant association, namely journal IF, 5-year citation index, cohort size, results included into guidelines.

The survey tested the respondents in their most common reasons for adopting a new practice. First came the availability of a RCT-manuscript (two-thirds of respondents), followed by having assisted the new approach in a live operation (18%), hearing a presentation by an expert in the field (12%), and having watched a surgical video (4%). None of the respondents declared not to be open for novel practices.

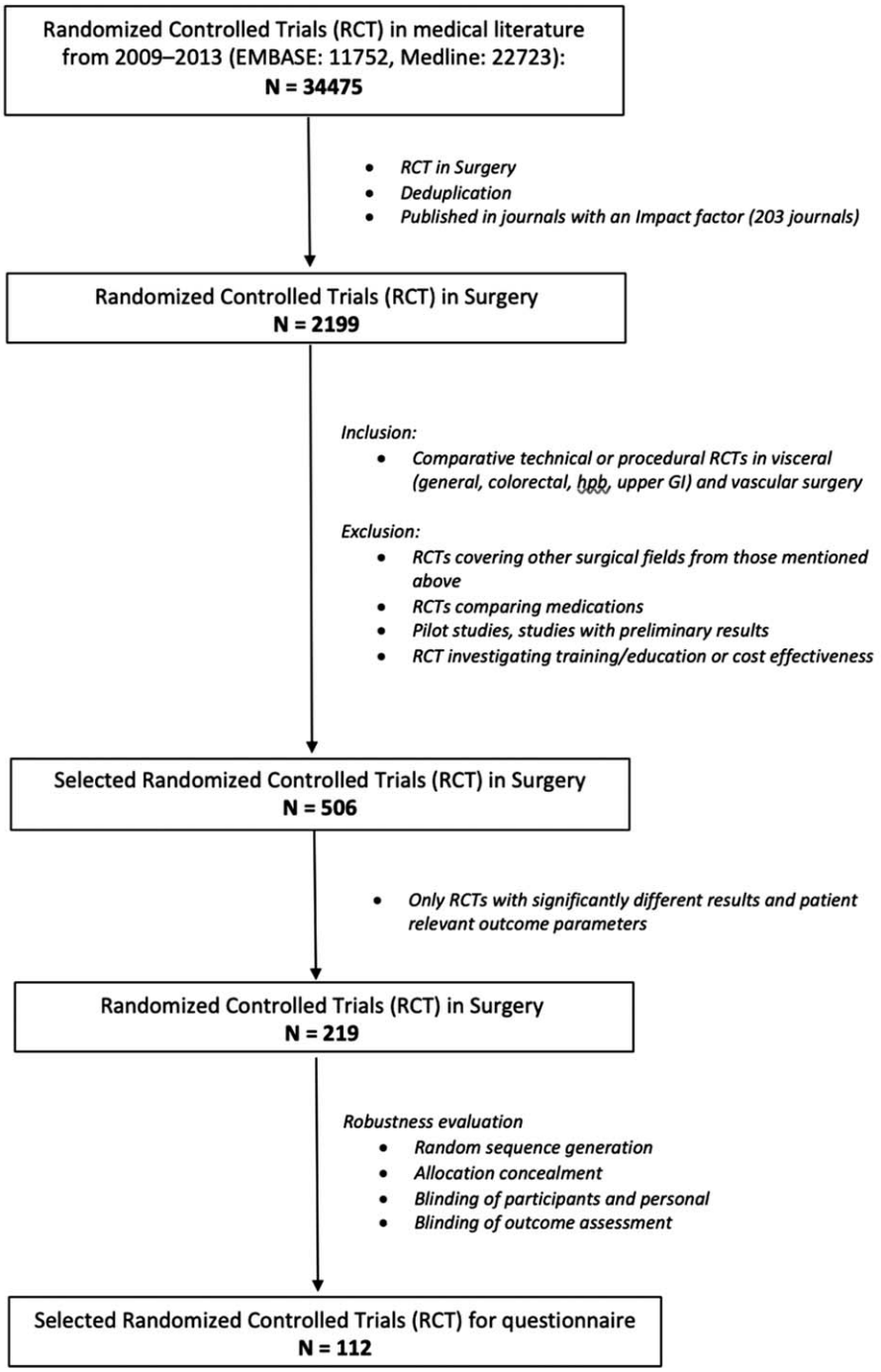

FIGURE 1. Flow chart of RCT selection. After screening 34,475 RCTs published during the time period 2009 to 2013, we identified 2199 trials in the field of surgery (6.4%), which were published in recognized journals benefiting from an Impact Factor. Further selection restricted the study to only comparative technical or procedural RCTs in the domains of general, colorectal, hepatobiliary, upper GI, and vascular surgery, leaving 506 eligible trials, of which 219 produced results that were statistically different between treatment/procedure groups. Robustness evaluation regarding randomization and blinding using Cochrane criteria resulted in a final delineation of 112 RCTs that could be incorporated into our questionnaire.

Indicated reasons for not adopting a new procedure were primarily doubts regarding the validity of the study (40%). Less than a fourth of the respondents (24%) mentioned that the presumption of low clinical relevance would be a motive for dismissal of the RCT finding. Unknown long-term outcomes or fear of complications associated with certain procedure were mentioned by 15% of the surgeons; another 15% regarded the learning curve as a major obstacle for the adoption of the recommended procedural change. None of the polled surgeons regarded higher cost or disapproval of the new method by the patients to constitute a reason for not adopting a recommendation from a RCT. When asked if they had ever implemented a new technique after only seeing the new method in a video presentation, nearly half of the surgeons (46%) answered positively. More than half (55%) also stated to have undertaken a new procedure after reading about it in an RCT in the past (Table 4).

DISCUSSION

This study demonstrates the paucity of RCTs emanating from the surgical community, and even more worrisome is the observation that most high-level available information from those trials recommending changes in practices is not taken into account.

TABLE 1. Overview RCTs With Low Risk of Bias (n = 112)

Journals (n)	15
Year of publication	2009–2013
Impact factor at time of publication, median (range)	3.1 (0.83–7.9)
RCT (n)	112
Countries of origin (n)	30
Citation Index (5 yr), median (range)	54 (3–474)
Participating centers, median (range)	1 (1–41)
Cohort size nr. of total patients, median (range)	100 (24–1000)

Less than half of the members of the ESA may adhere to the recommendations of high-quality RCTs with, however, a large variation among trials (0–90%) (Fig. 2) depending on the fields examined; the field of colorectal surgery showing a slightly better adherence to RCTs compared to the others. Surgeons regard good RCTs as the principal reason for a change in surgical policy, but they mitigate their enthusiasm by indicating that their outlook of the methodology represents the main impediment precluding adoption of a trial's recommendations.

Only 6% of all RCTs cover a surgical topic, and reticence in embarking in RCT mostly relies on difficulties in the standardization of surgical techniques with the lack of equipoise justifying randomization; this from both from surgeon *and* patient perspectives.[22] Also, blinding of patients, health care providers, and outcome assessors to reduce bias is not only difficult, but often impossible.[23] In addition, RCTs are time- and cost-consuming. Hence, they may simply be unsuitable to underscore the exploration, or implementation, of novel techniques, as these can change rapidly so that data may become of less interest to surgeons once they are finally published.[24–27] The notion that surgical practice may outrun RCTs is illustrated by minimally invasive revolution over the past 3 decades, led by the worldwide adoption of laparoscopic cholecystectomy in the early 1990s.[28] Quantitative observational methods widely used in aviation and automobile industry, such as Statistical Process Control, as well as the IDEAL framework, provide solutions to many of the problems inherent to RCTs and assure patient safety and quality assessment during introduction of new technology in surgical procedures.[29,30] Statistical Process Control (SPC) helps in monitoring new procedures in a predefined frame, as has been successfully shown in manufacturing lines. It allows early detection and prevention of problems and could be transferred to the operating theater to monitor the introduction of novel procedures in surgery.[31]

TABLE 2. Characteristics Survey

Respondents of survey (n)	130
Gender (male), % (n/N)	82% (107/130)
Years of experience, median (range)	16 yr (0–48)
Respondents' specialization	
General surgery, % (n/N)	27% (35/130)
Colorectal surgery, % (n/N)	22% (29/130)
HPB surgery, % (n/N)	22% (28/130)
Upper GI surgery, % (n/N)	13% (17/130)
Vascular surgery, % (n/N)	6% (8/130)
Transplant surgery, % (n/N)	6% (8/130)
Thoracic surgery, % (n/N)	1% (1/130)
Cardiac surgery, % (n/N)	1% (1/130)
Trauma surgery, % (n/N)	2% (3/130)
Journals of RCT publication (n)	15
Year of publication	2009–2013
Impact factor at time of publication, median (range)	3.3 (1.23–7.9)
RCT included in survey (n)	36
Citation Index (5 yr), median (range)	85 (24–474)
Participating centers, median (range)	1 (1–31)
Cohort size nr. of total patients, median (range)	133 (28–856)
General surg. RCT included, % (n/N)	19% (7/36)
Colorectal RCT included, % (n/N)	42% (15/36)
HPB RCT included, % (n/N)	28% (10/36)
Upper GI RCT included, % (n/N)	8% (3/36)
Vascular surgery RCT included, % (n/N)	3% (1/36)
Questions for survey (n)	22
General surg. questions, % (n/N)	27% (6/22)
Colorectal surg. questions, % (n/N)	32% (7/22)
HPB surg. questions, % (n/N)	27% (6/22)
Upper GI surg. questions, % (n/N)	9% (2/22)
Vascular surg. questions, % (n/N)	5% (1/22)

While the complexity of surgical RCTs has been extensively addressed,[32–35] the adoption of their results into clinical practice has not. Here, we show that less than half of responding ESA members is ready to accept a change of surgical policy based on a certain RCT. This acceptance rate may be even overestimated, as the vast majority of ESA members have positions in academia where adherence to outcomes of clinical research might penetrate earlier, and surgical policy might be expected to be less dominated by individual surgeons' preference. This leaves room for the possibility that the actual ''acceptance rate'' of surgical RCT results in general surgical practice might even be significantly lower.

The great variation in adopting certain RCT results over all fields of surgical specialization is interesting. Particularly, there appeared to be hardly any ''grey area'': respondents either embraced the results of a specific trial or refuted it. Someone can only speculate as to the causes underlying this observation. Apparently, some trials confirm the current practice of the individual surgeon or are considered so convincing that the surgeon is willing to change his or her practice accordingly. Another matter is timeliness. It has to be accepted that achieving change takes time, and that several RCTs on the same topic producing similar outcomes may be necessary to convince the surgical community to change policy. This might explain the remarkably low acceptance of 2 high-quality RCT-based technical recommendations regarding pancreatico-jejunostomy in Whipple's procedure.[36,37] An RCT published 2011 in *Ann Surg* recommended an external intrapancreatic stent in Whipple procedures of soft pancreatic texture and a nondilated pancreatic duct.[36] This recommendation was adopted by only 25% (19/76; CI 0.016–0.36). The second example refers to the dual institutional trial published 2009 in the *Journal of American College of Surgeons* advocating an invagination technique in order to reduce fistula rates by half, when compared to the duct-to-mucosa pancreaticojejunostomy.[37] Only 10% (8/80 CI: 0.05–0.19) of the responding academic surgeons have adopted this technique (Table 3). In general, the minimally invasive surgical techniques appear to have found widespread acceptance in surgeons' daily practice. For example, in colorectal surgery many RCTs published over decades and consistently showing favorable results of laparoscopic procedures over the open ones have finally led to widespread acceptance and adoption of the minimal invasive approach by the surgical community.[38–44] Accordingly, 85% and 94% of the responding surgeons opted for a laparoscopic approach as their standard technique in resections for colorectal cancer and diverticulitis, respectively.

The main observation of this study is that clinical practice does not seem to adapt readily to the outcomes of surgical RCTs. The most commonly mentioned reason for nonacceptance was skepticism regarding the validity of the applied methodology, followed by RCT results believed to be of low clinical relevance. Indeed, RCTs are rarely considered to reflect the ''real world,'' amongst others due to adherence to stringent in- and exclusion criteria, affecting the generalizability of trial outcomes.[10] As an alternative, large data sets from national registries or audits could be used to assess surgical outcomes, which – when well conducted – may represent a more realistic evaluation of daily surgical practice than RCTs.[45] The discovery of increased severe bile duct injuries with the introduction of laparoscopic cholecystectomy was only possible through a well-conducted registry and would have remained undetected in RCTs due

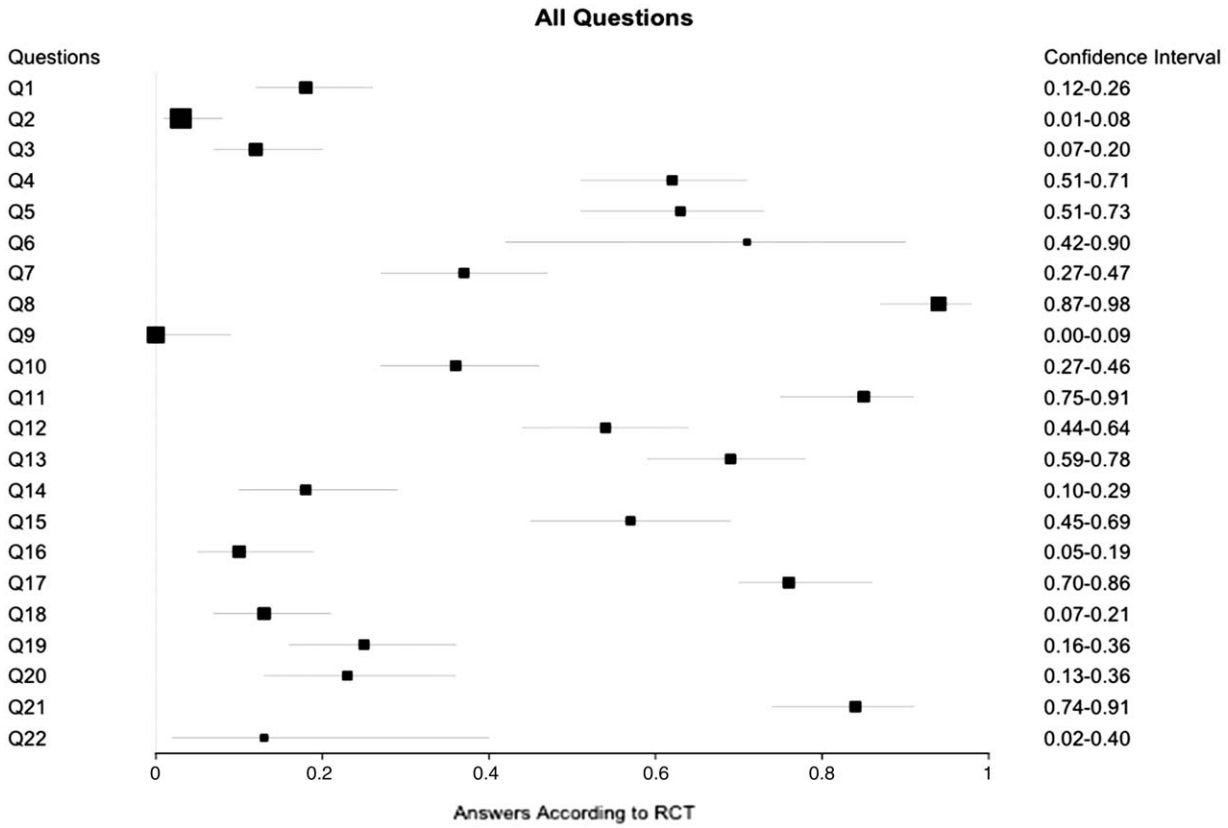

FIGURE 2. Questions and ''corresponding'' answers of the pulled academic surgeons. This figure shows the wide range between asked questions and ''corresponding'' (according to RCT recommendation) answers. If answers corresponded with RCT recommendation, they are located to the right side of the graph, if not, on the left side.

to their small sample size. Among 34,490 cholecystectomies, an incidence of 0% to 4% was discovered, with bile duct injuries being ×10 higher in laparoscopic cholecystectomies than what was observed with the open procedure.[46]

Other reasons for not implementing recommended practices may include organizational hurdles and/or financial considerations. One example is the recommended intraoperative rendez-vous procedure for patients with concomitant gallbladder- and common bile duct stones, advocated by only 14/109 respondents. Also, though not included in the present survey, RCTs favoring robotic techniques are coming into view, but the application of robotic systems has hitherto been hampered by significant cost-concerns in many institutions.[47] On the other hand, RCT results may be met with skepticism, when they contradict the impression or expectations of the professionals. An interesting example is the endovascular treatment of abdominal aneurysms: while the clinical experience is that EVAR significantly reduces mortality and morbidity at acceptable costs, this treatment was shown not to be cost-effective in long-term RCT follow-up studies, and in RCTs thus far mortality rates in acute cases are not significantly better compared to open repair.[17,48] Furthermore, the role of industry in pushing certain technology forward should be considered as a well-established major source of bias.[49]

Meaningful RCTs that advocate for a change in clinical practice should include relevant patient outcome data as primary endpoint and be adequately powered. They need to fulfill the Cochrane criteria including important items such as random sequence generation, allocation concealment, blinding of participants, and personal as well as blinding of outcome assessments. With our thorough selection process we did include only those ''robust'' RCTs with a statistically significant difference in results between groups to overcome equipoise of one surgical procedure over another. Nevertheless, recommendations of those highly selected RCTs were adopted in only 47%. Forty percent of respondents expressed doubts regarding the validity of the methodology used in RCTs. It is this skepticism which opens a gap between high quality, patient relevant recommendations, and the adoption into clinical practice.

The question remains how we can increase penetrance and adoption of recommendation generated by RCTs into clinical practice. In a first attempt surgeons must be convinced of the surgical procedure. This can be achieved best by making results visible, available to the busy surgeon. As our survey revealed, eye-catching visual abstracts have high potential in getting surgeons' attention and already many journals are becoming active on social media. There is an imminent need for stronger emphasis on video sessions as 46% of our respondents implemented a new surgical technique after having seen a video presentation. Also, novel ways of evaluating surgical techniques should be embraced, in order to facilitate convincing surgeons of their value. As an example, the method of statistical process control was recently reported by a group of urologists to prospectively monitor patient safety during the learning phase of robotic kidney transplantation.[31]

By nature, any survey suffers from shortcomings, including possible lack of representativity/generalizability and inherent bias regarding the questions, the selected RCTs, and the respondents' background. Unfortunately, we were unable to identify factors that might determine the adoption of surgical RCT results. Nonetheless, it represents a rare analysis of the impact of RCTs on daily surgical practice, inviting

TABLE 3. Survey Questions

Nr.	Questions	Corresponding Answers % (n/N)
General surgery		
Q1	Preferred technique in minimally invasive inguinal hernia repair: TEP vs. TAPP	71% (10/14)
Q2	Timing of surgery in acute cholecystitis	63% (47/75)
Q3	Port-à-cath implantation technique	62% (60/97)
Q4	Diathermy vs. scalpel for skin incision	18% (23/130)
Q5	Triclosan-impregnated polydioxanone sutures for lowering wound infection rate	12% (16/129)
Q6	Approach on mesh fixation in Lichtenstein procedure	3% (3/111)
Colorectal Surgery		
Q7	Primary surgical approach for elective sigmoid resection for diverticulitis	94% (93/99)
Q8	Approach of colectomy for colorectal cancer	85% (78/92)
Q9	Mechanical bowel preparation in patients prior to rectal cancer surgery	69% (67/97)
Q10	Preferred method of ileostomy wounds closure	54% (53/98)
Q11	Preferred approach in sigmoidal perforated diverticulitis (Hinchey III/IV): Hartmann's vs. primary anastomosis	37% (37/101)
Q12	Preferred treatment of acute left-sided malignant colonic obstruction	36% (36/101)
Q13	Preferred treatment of anism	0% (0/52)
HPB surgery		
Q14	Standard technique for minimal-invasive cholecystectomy	76% (86/109)
Q15	RFA vs. resection in HCC treatment	57% (43/75)
Q16	External intrapancreatic stent in difficult pancreatico-jejunostomy with small pancreatic duct and a soft pancreas during Whipple procedure	25% (19/76)
Q17	Preferred inflow occlusion technique in liver resection for HCC	18% (13/72)
Q18	Management approach of concomitant gallbladder and common bile duct stones	13% (14/109)
Q19	Preferred anastomotic technique for pancreatico-jejunostomy in Whipple procedure	10% (8/80)
Upper GI surgery		
Q20	Reconstruction method after distal gastrectomy	84% (69/82)
Q21	Omental pedicle flap around the esophagogastric anastomosis after esophagectomy	23% (13/57)
Vascular surgery		
Q22	Laparoscopic vs. open approach for aortobifemoral bypass in severe aorto-iliac occlusive disease	13% (2/16)

possible alternatives to RCTs in the evaluation of surgical innovation. In addition, the assertion that almost half of the respondents have adopted a new technique after merely seeing a video presentation gives rise to the concern that more modern ways of distributing scientific results other than traditional presentation at conferences and in journals should be seriously monitored to increase surgeons' attention novel developments in the field at an earlier stage. Ideally, RCTs would need to be corroborated by data from registries, large cohort studies, video presentations, and long-term and cost-effectiveness analyses, in order to enhance acceptance of their outcomes.

In conclusion, procedural surgical RCTs are still embraced as the highest level of surgical evidence. Nonetheless, they carry a highly variable degree of adoption in daily surgical practice. More emphasis should go to ways to better convince the surgical community of the evidence produced, including modern methods of disseminating RCTs outcomes, corroborating evidence from similar RCTs, and additional tools to evaluate surgical innovations.

TABLE 4. Additional Survey Questions Asking for Personal Factors for or Against Adoption of RCT Recommendations

Procedure Implementation Practices*	
Reason for implementation of practice	
Manuscript of a randomized controlled trial, % (n/N)	66% (86/130)
Assisting live operation, % (n/N)	18% (23/130)
Lecture on new procedure by expert, % (n/N)	12% (16/130)
Surgical video, % (n/N)	4% (5/130)
No change of surgical practice anymore, % (n/N)	0% (0/130)
Reasons not to adopt practice	
Doubt validity of methodology, % (n/N)	40% (52/130)
Believe have low clinical relevance, % (n/N)	24% (31/130)
Unknown outcomes considered as unclear risks, % (n/N)	15% (20/130)
Learning curve, % (n/N)	15% (19/130)
Inconvenient new procedural technique, % (n/N)	6% (8/130)
Method not accepted by patients, % (n/N)	0% (0/130)
Fear of cost, % (n/N)	0% (0/130)
Previous Implementations of new practices	
Implemented new technique after only video presentation, % (n/N)	46% (60/130)
New technique after only reading a RCT, % (n/N)	55% (72/130)

*General information: more than 1 possible answer.
n/N indicates numerator/denominator; %, percent.

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DISCUSSANTS

Fabrizio Michelassi (New York, USA):

Thank you for asking me to comment on this special lecture, which looks at the efficacy of technical or procedural randomized control trials (RCTs) in changing current surgical practices. The authors have concluded that surgical RCTs have a low impact on daily surgical practice, and that the diffusion of new techniques and modern media, such as videos, is preferred.

Randomized control trials have long been considered the gold standard for practice-changing research. Although they have clear benefits, such as providing direct comparisons between variables, and limiting bias and confounders, they have many limitations as well. Several pitfalls include the difficulty of achieving a sample size sufficient to power the study to be statistically significant and the fact that the cohort may not be reflective of the general population, once inclusion and exclusion criteria have been considered. In the end, a surgeon may not find the results applicable to their patients or feasible to implement in their practice.

Operative videos have become a fast and inexpensive way to share and learn novel surgical techniques. As visual learners, who are often trained with the mantra of ''see one, do one, teach one,'' it is unsurprising that surgeons would be willing to accept this learning method. Junior surgeons can observe and adopt more efficient techniques for complex scenarios or watch a video on a unique procedure, which they may not have encountered in practice. Similarly, experienced surgeons are able to observe an innovative technique by watching a video and replicating it using a learning method that is similar to the one they used during their training.

It is interesting that when the authors asked the members of the European Surgical Association what their most common reasons for adopting a new practice are, the first reason was the availability of a RCT in 67% of cases, underscoring the validity of this type of trial. So, how do the authors reconcile this difference? Is it possible that surgeons, who are cautious of deviating from standard and proven practices, require more than just one single result to change their techniques? Is it possible that changing practice will continue to require a combination of different evidence: randomized clinical trials; analysis; and discussions, such as the ones we have had here for the past two days over social media and other diffusion modalities?

Thank you for the honor to discuss this special lecture presentation.

Response From Christian Oberkofler (Zurich, Switzerland):

Professor Michelassi, thank you very much for your thoughtful comments. While the hurdles and barriers of surgical RCTs are well known and have been experienced by many of us, the adoption of their results into clinical practice has never been investigated so far. Here, for the very first time, we present an analysis on possible reasons why recommendations of RCTs find their way into the adoption of a clinical practice or not. As you mentioned, surgeons are prone to be visual learners, and therefore, our findings on the high impact of visual abstracts and videos on the clinical adoption of a new surgical procedure are somehow intuitively expected.

Nevertheless, RCTs are still perceived as the gold standard of clinical research. This fact may have led to the logical answer of ESA members as per their most common reason for adopting a new practice: the availability of an RCT.

As I presented, there is a gap between meaningful recommendations drawn from academic clinical research and the clinical adoption of these recommendations into daily practice. Looking at the results of our survey, this gap is larger than expected and the future challenge our surgical community has to undertake is to close this gap by selling our RCTs better. Social media, such as Twitter, Facebook, and LinkedIn, could play an important role in this.

I do agree with your statement that one RCT alone may generally be insufficient to overcome the skepticism of experienced surgeons, who have developed their practice into one that they have become confident with over many years. This may be why the minimal invasive approach in colorectal surgery is now widely accepted, after more than 3 decades of repeated RCTs showing the favorable results of laparoscopic procedures over the open ones. Thanks again for your valuable comments.

Han-Kwang Yang (Seoul, Republic of Korea):

The value of this study would be a rare analysis of the impact of RCTs on daily surgical practice.

The common adoption of a new surgical technique or surgical decision is based on a treatment guideline. The guideline is formulated by the sum of all of the evidence, including the RCT. One good RCT is not necessarily directly reflected in the guideline. That could explain why even academic ESA surgeons in this survey adopt only half of the RCT results.

The issues of accepting a new surgical procedure as standard and properly executing a new surgical procedure are different.

In this sense, the authors' question as to whether the RCT, live surgery assistant or act of watching a video, in order to adopt a new surgical procedure, does not look appropriate.

I hope that this study result does not discourage the value of surgical RCTs.

Rather, I would like to suggest that authors discuss the following points:

First, how to design good surgical clinical study RCTs (vs. 6%)?

Second, how to define good RCTs, which may affect my practice?

Third, workshop videos or hands on to help the learning curve?

Finally, the authors suggest that there are ''alternative methods of evaluating and monitoring surgical procedures, such as those available in the aviation and automobile industry'' (ie, the Statistical Process Control or SPC). Obviously, these kinds of approaches need to be tested in many cases, in order to draw valuable conclusions. How about the concern about the balance between well-defined RCTs with limited patients versus thousands of patients? In addition, in contrast to the other industries, each case may not be as simple to compare. Are there any examples of SPC in the field of surgery?

Response From Christian Oberkofler (Zurich, Switzerland):

Thank you Professor Yang, it is a great honor to have your input on our analysis of the adoption of surgical procedural RCTs in daily clinical practice. A single well-conducted RCT is certainly the best way to produce valid evidence on the effectiveness of interventions and can overcome equipoise. In this context, following RCTs can also be seen as ethically doubtful, as equipoise is not given anymore. Therefore, in my opinion, a ''high quality'' RCT should trigger a change in clinical practice.

With our survey, we did not intend to temper the value of surgical RCTs, but rather draw attention to the gap between high-quality patient relevant recommendations and daily clinical practice.

With regards to your first question, good surgical clinical study RCTs need to have a relevant patient outcome as the primary endpoint as well as respect the Cochrane criteria of conducting RCTs.

Regarding your second question, we did try to answer this question in our survey, including only well-designed, ''good'' RCTs. Unfortunately, in our regression analysis, we were unable to correlate any factor favoring the adoption into clinical practice.

Concerning your third question, it is our perception that video workshops and hands on training do find a broad acceptance within the surgical community, and in my opinion, they will become increasingly important to convey novel techniques and approaches.

Finally, SPC has been described for the evaluation of novel surgical procedures in the literature. The main reason for us to propose such a methodology is to use preset criteria and limitations during the evaluation, that is before the implementation of a new technique.

Arnulf Hölscher (Frankfurt, Germany):

First, 40% of the respondents indicated doubts regarding the validity of the study as a reason for not adopting a new procedure. Could you explain the reasons for these doubts a bit more?

Second, nearly 1 quarter of the respondents named low clinical relevance as a reason for the dismissal of the RCT findings. Was there a higher rate of adoption for the results of the RCTs with obviously high clinical relevance?

Response From Christian Oberkofler (Zurich, Switzerland):

Thank you Professor Hölscher, it is a great honor to have you as a discussant of our survey.

Indeed, 40% of the respondents did not adopt a new surgical procedure, due to their skepticism regarding the validity of the methodology of the RCTs. As we did not ask respondents on their reasons of mistrust against RCTs, I can only speculate. Surgeons still learn their craft through apprenticeship. They stick to their own experience and become comfortable with a specific procedure, and therefore, they may initially express skepticism toward novel techniques.

In our linear regression model, we aimed to find a correlation between factors of an RCT and their adoption into clinical practice. Our highly selected RCTs all have clinically relevant outcomes, but it was demonstrated that their recommendations still had a relatively low adoption rate.